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**510(k) SUMMARY**  
(As required by 21 C.F.R. 807.92)

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**Date :** December 18, 2001

**Submitter :** ANTHOGYR  
164, rue des 3 lacs  
74700 Sallanches - FRANCE  
Tel : 33 (0)4 50 58 02 37  
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Establishment registration number : #8020776

**Contact**

CHAIRMAN AND MANAGING DIRECTOR : Mr Claude ANTHOINE  
Tel : 33 (0)4 50 58 02 37  
E-Mail : prod@anthogyr.com

**Device Name**

<u>Proprietary Name :</u>	FIBIOCORE
<u>Device Trade name :</u>	FIBIOCORE
<u>Common/Usual Name :</u>	Glass Fiber composite root canal post
<u>Proposed Classification Name :</u>	Dental root canal post

**Device Classification**

<u>Class :</u>	I
<u>Classification Regulation :</u>	21 CFR 872.3810
<u>Product Code :</u>	76 ELR

**Performance Standards & Testing**

Standard ISO 10993-5 "Biological evaluation of medical devices - Tests for Cytotoxicity : in vitro methods" was conducted and shows no evidence of a cytotoxic response. Mechanical tests were conducted in conformance with ISO 3597-2 (Three-point Bending Standards). The results showed the material to be suitable for root canal posts. Others Mechanical tests were conducted to characterize the material.

**Predicate Device - Substantial Equivalence**

The modified device is substantially equivalent to the previously cleared Carbotech Snowpost (K012354), Bisco UM Aesthetic Post (K945370), Coltene ParaPost Fiber White (K000311), Jeneric/Pentron FibreKor Post (K983266), and the Harald Nordin Glassix post (K003221) devices.

The modified device is substantially equivalent in quality of mechanical characteristics, of mechanical safety, of materials, of design, of performance and of indications for use.

**Modifications**

The primary differences are minor changes to the material and dimensions.

**Intended Use of the subject Devices**

The modified device has the same intended use as the legally marketed predicate devices herein referenced. The FIBIOCORE composite posts are intended for use by dentists to give retention for reconstruction of non-vital teeth. The device is intended to be cemented into the root canal of a tooth to stabilize and support a restoration.

**Technological Characteristics**

The modified device has the same technological characteristics as the legally marketed predicate device mechanically supporting reconstruction.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

JUL 3 2002

Mr. Claude Anthoine  
Est. ANTHOYR  
Chairman and Managing Director  
164 Rue Des 3 Lacs  
74700 Sallanches,  
FRANCE

Re: K020431

Trade/Device Name: FIBIOCORE Glass Fiber Composite Posts  
Regulation Number: 872.3810  
Regulation Name: Root Canal Post  
Regulatory Class: I  
Product Code: ELR  
Dated: May 9, 2002  
Received: May 9, 2002

Dear Mr. Anthoine:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

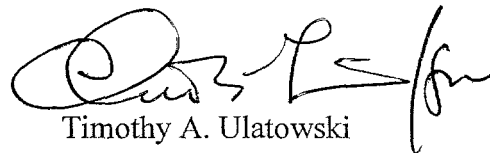
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



Timothy A. Ulatowski  
Director

Division of Anesthesiology, General Hospital,  
Infection Control and Dental Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

K 020431

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## INDICATIONS FOR USE STATEMENT

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510(k) Number :  
(if known)

Device Name: FIBIOCORE Glass Fiber composite posts

Indications For Use : The FIBIOCORE composite posts are intended for use by dentists to give retention for reconstruction of non-vital teeth.

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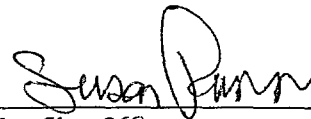
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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ☒   
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ☐



(Division Sign-Off)  
Division of Dental, Infection Control,  
and General Hospital Devices  
510(k) Number K020431